510(k) Summary

JUN 10 2013

Proprietary Name:	Hoffmann LRF (Limb Reconstruction Frame) System
Common Name:	External Fixation Device
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030
Regulatory Class:	Class II
Product Codes:	KTT-Appliance, fixation, nail/blade/plate combination, multiple components
Sponsor:	Stryker Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland
Contact Information:	Estela Celi Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-3461 estela.celi@stryker.com
Date Prepared:	March 28, 2013

Description:

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market additional components as a line extension to the currently marketed Hoffmann LRF (Limb Reconstruction Frame) System, previously cleared in K113327. The Hoffmann LRF System is an external fixation device that consists of carbon and aluminum full/open rings and ring segments, aluminum foot rings, threaded rods and threaded rod connecting nuts, telescopic struts, static struts and connection bolts, posts and connecting nuts, wires and wire bolts, wire bolt offset adapters, pin bolts and pin adapters, and washers. The additional components will consist of the following: carbon foot ring, foot arch, hinge coupling and compatibility with the previously cleared Hoffmann 3 couplings. This external fixation system may also be used with

the components of other Stryker Trauma AG external fixation systems such as the Monticelli Spinelli External Fixation System, the Hoffmann II MRI External Fixation System, and the Stryker Trauma Pelvic Set and in conjunction with commercially available Apex Pins, Hoffmann II External Fixation 90° Post, Carbon Connecting Rod and Miami Post.

Intended Use:
The Hoffmann LRF (Limb Reconstruction Frame) System is intended for fixation of fractures, joint contractures, fusions, limb lengthening, deformity correction, bone and soft tissue reconstruction in pediatric patients and adults

Indications:
The Stryker Hoffmann LRF (Limb Reconstruction Frame) System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and Closed Fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis or non-union of long bones
- Limb lengthening by epiphyseal or metaphyseal distraction
- Correction of bony or soft tissue deformity
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures of the distal radius

The Stryker Hoffmann LRF System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Lisfranc dislocations

Summary of Technologies:
Device comparison showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the following predicate devices:

- Hoffmann LRF (Limb Reconstruction Frame) System- K113327
- External Fixation System (Smith and Nephew)- K031181

Non-Clinical Testing:
Non-clinical laboratory testing was performed for the Hoffmann LRF (Limb Reconstruction Frame) System on the additional components and component compatibility. Testing was performed with compliance to ASTM F1541-02 – "Standard Specification and Test Methods for External Skeletal Fixation Device." Testing demonstrated that the Hoffmann LRF (Limb Reconstruction Frame) System added components are substantially equivalent to the predicate device components. Testing included the following:

- Static Cantilever Bending Test-Carbon Foot Ring
- Static Compression Test- Foot Arch
- Static Cantilever Test-Hinge Coupling
- Dynamic Test-Frame Construct
- Compatibility Engineering Evaluation

Clinical Testing: Clinical testing was not required for this submission.

Conclusion: The Hoffmann LRF (Limb Reconstruction Frame) System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 10, 2013

Stryker Trauma AG
% Ms. Estela Celi
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K130907
Trade/Device Name: Hoffmann LRF (Limb Reconstruction Frame) System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: April 11, 2013
Received: April 12, 2013

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130907

Device Name: Hoffmann LRF (Limb Reconstruction Frame) System

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices